

510(k) Summary

K090100

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Submitted by: Chitogen Inc.
7255 Ohms Lane
Minneapolis, MN 55439
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Contact Person: Janna Bereuter

Date Prepared: 15 December 2008

Proprietary Name: Chitogen Inc. SoftSeal-STF

Common Name: Topical Hemostasis Pad

Classification: Unclassified

Classification Name: Topical Wound Dressing Pad

Product Code: FRO

Predicate Device: Scion Cardio-Vascular Clo-Sur P.A.D K-032986

Device Description: SoftSeal-STF is a sterile topical pad, packaged in a foil pouch, and sterilized with gamma irradiation to a SAL of 10^{-6} .

Intended Use: The SoftSeal-STF pad made by Chitogen Inc. is intended for the local management of topical bleeding wounds, the rapid control of bleeding in patients following hemo-dialysis, or in patients on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose bleeds, and the skin surface puncture sites resulting from vascular access procedures, percutaneous catheters or tubes.

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Technological Characteristics: The Chitogen Inc., SoftSeal-*STF* pad is a non-woven pad made of a proprietary formulation of poly-D-glucosamine and poly-N- acetylglucosamine derived from chitosan. The natural biological property of this material gives the SoftSeal pad an advantage as an effective bacterial barrier while providing for an optimal wound-healing environment. Several biomedical applications of poly-D-glucosamine and poly-N- acetylglucosamine have been reported. The studies represent research on the safety and use of these materials, published over a period of decades by scientists from around the world. This large body of scientific literature satisfies the requirement that a general recognition of safety requires common knowledge about the substance throughout the scientific community. This formulation has many useful and advantageous properties in their application as a wound dressing, namely biocompatibility, biodegradability, hemostatic activity, anti-infectional activity. The technological characteristics of the SoftSeal-*STF* pad are the same as the predicate device (Scion Cardio-Vascular, Inc., Clo-Sur PAD). The Chitogen SoftSeal-*STF* pad works in the same manner as the approved predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 11 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Chitogen, Inc.
% Ms. Janna Bereuter
Director, Clinical and Regulatory
Affairs
7255 Ohms Lane
Minneapolis, Minnesota 55439

Re: K090100

Trade/Device Name: SoftSeal-STF
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 12, 2009
Received: January 29, 2009

Dear Ms. Bereuter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090100

Device Name: SoftSeal-STF

Indications for Use:

SoftSeal-STF is indicated for use in the management of bleeding wounds such as skin lacerations, vascular access sites, or percutaneous catheter or tube sites. SoftSeal promotes the rapid control of bleeding for patients on hemodialysis and patients on anticoagulation therapy.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kraemer for MXM 3/10/2009

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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